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| EXAMINER |
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PRIDDY, MICHAEL B

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3733

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09/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/789,367 | Applicant(s) GANZ ET AL. | |
| | Examiner Michael B. Priddy | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) 40-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 and 87-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the invention of Group I in the reply filed on 07/16/2007 is acknowledged. Claims 40-86 are withdrawn from further consideration while an action on the merits of the elected claims, 1-39 and 87-95 follows.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cutting tool, window template, implant base and tool for installing the implant base must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 88, 89 and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Regarding claims 3 and 4, it is not possible to know how the dimensions of a particular patient or radiographic data therefrom structurally limit the bone graft of claim 1.

Regarding claim 88, it is unclear how a particular patient has unique bone graft dimensions.

Regarding claim 89, the phrase "coordinated with dimensions of the sinus" structurally defines the bone graft.

Regarding claim 91, it is unclear how the phrase "incapable of cutting bone but capable of cutting soft tissue" structurally limits a cutting tool.

Claim Rejections - 35 USC § 101

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 5 is rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 5, line 2, Applicant positively recites part of a human, i.e. "external surfaces facing adjacent natural bone in a patient". Thus claim 5 includes a human within its scope and is non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In *re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11-14, 19-21, 23, 27, 28, 30-34, 36, 38, 39, 87-92 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by McKay (U.S. 5,972,368).

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McKay teaches a bone graft composite comprising a demineralized bone matrix (lines 36-37 of column 9); at least one hole corresponding to either or both of an intended position of an implant base and/or an attachment device; at least one feature 19 allowing the bone graft to be held by a gripping tool; the bone graft comprising a calcium phosphate ceramic (lines 9 & 10 of column 10); further comprising channels or patterns on a surface of the bone graft (threads); further comprising bone growth factor; a resorbable polymer in the form of polylactic acid (lines 43-44 of column 9); and wherein the graft is sterile (line 59 of column 7). McKay also discloses one cutting tool in the form of a reamer, a dilator and templates (line 49 of column 11). A dilator is incapable of cutting bone while being capable of cutting soft tissue.

Concerning the limitations of claims 2, the graft of McKay was manufactured to a shape which must have been desirable or it would not have been so manufactured.

Concerning the limitations of claims 3, 4 and 39, it is noted that the device of McKay appears to be substantially identical to the device claimed, although not disclosed as produced by the same process, therefore the burden is upon the Applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Concerning the limitations of claims 14 and 19, all matter, including demineralized bone and polymers is comprised of particles. For this reason, the Examiner contends that the graft comprising a matrix of particles joined to each other forming a three-dimensionally interconnected network where the particles are polymeric, is inherent to the disclosure of McKay.

Claims 1, 14, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimp (U.S. 6,846,853 B2). Shimp teaches a bone graft suitable to augment a sinus comprising particles of demineralized bone matrix joined to each other by a binder substance (lines 63-67 of column 3 and lines 1-5 of column 4).

Claims 1, 14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lo (WO 02/11781 A1). Lo teaches a bone graft suitable to augment a sinus, wherein the bone graft comprises synthetic material comprising a matrix of ceramic particles (see abstract) partially sintered directly to each other (lines 25+ of page 9) forming a three dimensionally interconnected network.

Claims 1, 22, 24, 25 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Khandkar et al. (U.S. 2003/0009225 A1). Khandkar et al. teaches a bone graft suitable to augment a sinus comprising both a nonresorbable, synthetic ceramic material and resorbable materials (in the form of a coating) in different proportions in different places within the bone graft (paragraph 0035).

Claims 1 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (U.S. 6,200,347). Anderson et al. teach a composite bone graft (Fig. 27) suitable to augment a sinus, wherein the bone graft comprises demineralized bone

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matrix 100 in a rigid form and channels 102 which extend into an interior of the bone graft; drill 72.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKay as applied to claim 1 above, and further in view of the following.

McKay teaches all of the limitations of the present invention except the bone graft being comprised of more than one piece. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of McKay having a plurality of pieces, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay as applied to claim 14 above, and further in view of the following. McKay teaches all of the limitations of the present invention except the mode of the pore size is between 10 microns and 25 microns; and the porosity being between approximately .2 and approximately .6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone graft of McKay such that the mode of the pore size is between 10 microns and 25 microns; and the porosity is between approximately .2 and approximately .6., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 35 rejected under 35 U.S.C. 103(a) as being unpatentable over McKay as applied to claim 34 above, and further in view of the following. McKay teaches all of the limitations of the present invention except the polymer being a comb polymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a comb polymer in place of the polylactic acid polymer disclosed, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKay as applied to claim 34 above, and further in view of the following. McKay teaches all of the limitations of the present invention except the polymer being a comb polymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a non-resorbable polymer in the device of McKay, since it has been held to be within the general skill of a worker in the art to select a known material on the

basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 87 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (U.S. 6,200,347) in view of Coates et al. (U.S. 5,989,289). Anderson et al. teach a kit comprising a composite bone graft (Fig. 27) suitable to augment a sinus, wherein the bone graft comprises demineralized bone matrix 100 in a rigid form and channels 102 which extend into an interior of the bone graft; an implant base 2; a drill 72.

Hence Anderson et al. teaches all of the limitations of the present invention except a tool for installing the implant base.

Coates et al. teach a related kit which includes an implant insertion tool (Fig. 6). It would have been obvious to one of ordinary skill in the art at the time of the present invention to include an insertion tool with the elements of Anderson et al. to facilitate implantation and avoid inserting the graft by hand.

Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKay as applied to claim 87 above, and further in view of Anderson et al. (U.S. 6,200,347). McKay teaches all of the limitations of the present invention except an additional article in the form of antibiotics.

Anderson et al. teach a related composite bone graft which may include a pharmaceutically active agent such as antibiotic. It would have been obvious to one of

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ordinary skill in the art at the time of the present invention to incorporate an antibiotic agent into the graft of McKay as taught by Anderson et al. to prevent infection at the implantation site.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 11, 12, 14-16, 20-28 and 32-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-10, 13-26 and 29-36 of copending Application No. 10/789,358. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claims is in their intended use.

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The manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art or copending apparatuses satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 10-12, 14, 16, 22-24 and 26-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 93-102 and 104-122 of copending Application No. 10/789,439. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 10/789,413 are more specific than the claims of the present application. More specific claims anticipate broader claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is 571-272-2243. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael B. Priddy

Michael B. Priddy
September 17, 2007


EDUARDO C. ROBERT
SUPERVISOR / PATENT EXAMINER